Clinical Trial Protocol
Iranian Registry of Clinical Trials

07 Nov 2026

Evaluating and comparing the efficacy of Fenugreek tablet and Mefnamic acid in the management of primary Dysmenorrhea, a randomized controlled trial

Protocol summary

Study aim

To compare the efficacy of fenugreek seed powder capsules with mefenamic acid in women aged 18–35 years with primary dysmenorrhea by evaluating menstrual pain intensity, onset and duration of treatment effect, menstrual blood loss, gastrointestinal symptoms, PANAS and IPAQ scores, and the efficacy and safety of fenugreek as an alternative or complementary treatment

Design

A phase II, randomized, double-blind, parallel-group, controlled clinical trial will be conducted in 80 patients with primary dysmenorrhea (40 participants per group). participants will be allocated to the fenugreek and mefenamic acid groups using permuted block randomization with 10 blocks of 8 participants.

Settings and conduct

conducted at Imam Ali Clinic in Shahrekord, Iran, among women aged 18–35 years with primary dysmenorrhea. participants randomly allocated to the groups and followed for two consecutive menstrual cycles. A double-blind; identical capsules coded and prepared by an independent person.

Participants/Inclusion and exclusion criteria

Women aged 18–35 years. Confirmed diagnosis of primary dysmenorrhea Regular menstrual cycles (21–35 days). Moderate to severe menstrual pain Willingness to participate and provision of written informed consent. No known allergy to fenugreek or mefenamic acid. No significant systemic diseases No secondary causes of dysmenorrhea washout period before enrollment.

Intervention groups

Intervention group (Fenugreek): receiving 335 mg fenugreek seed powder capsule three times daily from the first to the third day of menstruation Control group (Mefenamic acid): receiving one 250 mg mefenamic acid capsule three times daily from the first to the third day of menstruation. Capsules dentical in appearance, trial conducted under a double-blind design

Main outcome variables

Menstural pain intensity Duration of analgesic effect Time to onset of analgesic effect Menstural blood loss

General information

Reason for update

Acronym

IRCT registration information

IRCT registration number: **IRCT20260629070010N1**
Registration date: **2026-08-28, 1405/06/06**
Registration timing: **registered_while_recruiting**

Last update: **2026-08-28, 1405/06/06**
Update count: **0**

Registration date

2026-08-28, 1405/06/06

Registrant information

Name
Shirin Moazan
Name of organization / entity
Country
Iran (Islamic Republic of)
Phone
+98 990 098 6530
Email address
shirinmd1984@gmail.com

Recruitment status

recruiting

Funding source

Expected recruitment start date

2026-01-07, 1404/10/17

Expected recruitment end date

2027-01-07, 1405/10/17

Actual recruitment start date
empty
Actual recruitment end date
empty
Trial completion date
empty

Scientific title
Evaluating and comparing the efficacy of Fenugreek tablet and Mefnamic acid in the management of primary Dysmenorrhea, a randomized controlled trial

Public title
Comparing Fenugreek tablet and Mefnamic acid in primary Dysmenorrhea
Purpose
Supportive
Inclusion/Exclusion criteria
Inclusion criteria:
18 to 35 women Definitive diagnosis of primary dysmenorrhea (based on confirmation by a gynecologist and clinical history) Moderate to severe menstrual pain intensity (VAS score of 4 or higher or similar instrument) Consent to participate in the study and take the medication according to the physician's instructions.
Exclusion criteria:
Absence of ASA Class 1 and 2 diseases Absence of a history of allergy to fenugreek and mefenamic acid, based on participant self-reporting. Absence of any secondary cause for menstrual pain, such as endometriosis, uterine fibroids, or the use of an intrauterine device (IUD). Avoidance of painkillers or similar herbal medications during the treatment period. Not regularly taking hormonal medications, oral contraceptives, or other chronic medications that could interfere with the study results. No history of severe drug allergy Absence of a history of mental illness Not intending to become pregnant while breastfeeding or using contraceptives.
Age
From **18 years** old to **35 years** old
Gender
Female

Phase
3
Groups that have been masked

- Participant
- Care provider
- Investigator
- Outcome assessor

Sample size
Target sample size: **40**
Randomization (investigator's opinion)
Randomized
Randomization description
Randomization is carried out using a block randomization method. Participants are assigned to either the intervention or control group via the "Random Allocation" software, employing a permuted block randomization approach. A randomization list comprising ten blocks of eight participants each will be prepared and entrusted to an individual who is blinded to the intervention details and group assignments. Participants are allocated to these ten blocks of eight based on the timing of their enrollment, ensuring that each block contains four participants in the intervention group and four in the control group. This arrangement ensures that participants within each block enter the study and progress through follow-up stages at similar times, while maintaining a balanced group size throughout the study. Allocation concealment is employed to prevent allocation bias. A randomization list is prepared and entrusted to an independent individual who is unaware of the nature of the interventions or the group assignments. The researcher responsible for enrolling participants has no access to this list and remains unaware of the specific treatment assigned to each group. Following the assessment of eligibility criteria and the acquisition of informed consent, each participant's group assignment is determined by the independent individual and communicated to the researcher. This process eliminates the possibility of predicting or manipulating assignments prior to enrollment, thereby preserving the study's internal validity.
Blinding (investigator's opinion)
Double blinded
Blinding description
Allocation concealment is employed to prevent allocation bias. A randomization list is prepared and entrusted to an independent individual who is unaware of the nature of the interventions or the group assignments. The researcher responsible for enrolling participants has no access to this list and remains unaware of the specific treatment assigned to each group. Following the assessment of eligibility criteria and the acquisition of informed consent, each participant's group assignment is determined by the independent individual and communicated to the researcher. This process eliminates the possibility of predicting or manipulating assignments prior to enrollment, thereby preserving the study's internal validity. Both types of medication are prepared as capsules with identical packaging and appearance to ensure a double-blind study design (meaning neither the participants nor the researchers will know which medication is being administered). The capsules will be coded by an individual uninvolved in data collection or analysis (such as a pharmacist) and packaged in containers labeled only as "A" and "B," without identifying names. Neither the researchers nor the participants will be informed of the medication contents or participant group assignments until the data analysis is complete. Consequently, participants, the principal investigator, attending physicians, clinical care staff, researchers, and those involved in data collection and manuscript preparation will remain unaware of the medication contents and the composition of the intervention and control groups.
Placebo
Not used
Assignment
Single
Other design features

Secondary Ids

empty

Ethics committees

1

Ethics committee

Name of ethics committee
Research ethnic committee of Shahrekord University of Medical Science

Street address
Parastar, past Kashani 43, Hajar Hospital and Maternity Center

City
شهرکرد

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8816758915

Approval date
2026-01-07, 1404/10/17

Ethics committee reference number
IR.SkUMS.REC.1404.112

Health conditions studied

1

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

2

Description of health condition studied
Primary dysmenorrhea

ICD-10 code
N94.4

ICD-10 code description
Primary dysmenorrhea

Primary outcomes

1

Description
Menstrual pain intensity measured using the 10-cm Visual Analog Scale (VAS), with scores ranging from 0 (no pain) to 10 (worst imaginable pain).

Timepoint
Before intervention, 1, 2, and 4 hours after the first intervention, and on the second and third days of intervention

Method of measurement
Visual analog scale (VAS)

Secondary outcomes

1

Description
Gastrointestinal symptoms assessed using a researcher-made checklist

Timepoint
At the end of each menstrual cycle (Cycle 1 and Cycle 2)

Method of measurement
Researcher_made checklist

2

Description
Duration of analgesic effect (h)

Timepoint
1, 2, and 4 hours after the first dose; Days 2 and 3 of treatment

Method of measurement
Researcher_made checklist

3

Description
Time to onset of analgesic effect

Timepoint
1, 2, and 4 hours after the first dose; Days 2 and 3 of treatment

Method of measurement
Researcher_made checklist

4

Description
Menstrual blood loss measured using the Pictorial Blood Loss Assessment Chart (PBAC)

Timepoint
At the end of each menstrual cycle (Cycle 1 and Cycle 2)

Method of measurement
Pictorial Blood Loss Assessment Chart (PBAC)

5

Description
Mood status

Timepoint
Before the intervention and at the end of the second menstrual cycle

Method of measurement
Positive and Negative Affect Schedule (PANAS)

6

Description
Physical activity

Timepoint
Before the intervention and at the end of the second menstrual cycle

Method of measurement
International Physical Activity Questionnaire (IPAQ)

Intervention groups

1

Description
Intervention group: Participants will receive one oral capsule containing 335 mg of fenugreek (Trigonella foenum-graecum) seed powder three times daily (every 8 hours) from the first to the third day of menstruation. The capsules are manufactured by Barij Essence Pharmaceutical Company and are identical in appearance and packaging to the control capsules.
Category
Treatment - Drugs

2

Description
Control group: Participants will receive one oral capsule containing 250 mg of mefenamic acid three times daily (every 8 hours) from the first to the third day of menstruation. The control capsules are identical in appearance and packaging to the intervention capsules to maintain blinding.
Category
Treatment - Drugs

Recruitment centers

1

Recruitment center
Name of recruitment center
Emam ali
Full name of responsible person
Imam Ali Specialized and Subspecialized Clinic
Street address
Shariati Street, opposite the Tax Administration, Shahrekord, Chaharmahal and Bakhtiari Province, Iran
City
Shahre_kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8817984498
Phone
+98 38 3224 2696
Email
Shirinmd1984@gmail.com

Sponsors / Funding sources

1

Sponsor
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Shirin moazan
Street address
Kashani Boulevard, Shahrekord, Chaharmahal and Bakhtiari Province, Iran
City
Shahre_kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
8815713471
Phone
+98 38 3335 0080
Fax
+98 38 3334 9506
Email
International@skums.ac.ir
Grant name
Grant code / Reference number
Is the source of funding the same sponsor organization/entity?
Yes
Title of funding source
Shahre-kord University of Medical Sciences
Proportion provided by this source
100
Public or private sector
Public
Domestic or foreign origin
Domestic
Category of foreign source of funding
empty
Country of origin
Type of organization providing the funding
Academic

Person responsible for general inquiries

Contact
Name of organization / entity
Shahre-kord University of Medical Sciences
Full name of responsible person
Shirin moazzan
Position
Consultant
Latest degree
Specialist
Other areas of specialty/work
Gynecology and Obstetrics
Street address
Shariati Street, opposite the Tax Administration, Shahrekord, Chaharmahal and Bakhtiari Province
City
Shahre_kord
Province
Chahar-Mahal-va-Bakhtiari
Postal code
۸۸۱۵۷۱۳۴۷۱
Phone
+98 913 381 0365
Email
Shirinmd1984@gmail.com

Person responsible for scientific

inquiries

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
Shirin Moazan

Position
Associate professor

Latest degree
Specialist

Other areas of specialty/work
Gynecology and Obstetrics

Street address
Shariati Street, opposite the Tax Administration, Shahrekord

City
Shahre_kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
۸۸۱۵۷۱۳۴۷۱

Phone
+98 38 3224 2875

Fax

Email
Shirinmd1984@gmail.com

Person responsible for updating data

Contact

Name of organization / entity
Shahre-kord University of Medical Sciences

Full name of responsible person
فاطمه علیدادی

Position
Anesthesia assistant

Latest degree
Bachelor

Other areas of specialty/work
Anesthesiology

Street address
No 3, fifth Ave, Hatef Blvd, Shahre_kord city

City
Shahre_kord

Province
Chahar-Mahal-va-Bakhtiari

Postal code
8817984498

Phone
+98 990 098 6530

Email
fatylydady@gmail.com

Sharing plan

Deidentified Individual Participant Data Set (IPD)
No - There is not a plan to make this available

Justification/reason for indecision/not sharing IPD
There is no further information

Study Protocol
No - There is not a plan to make this available

Statistical Analysis Plan
No - There is not a plan to make this available

Informed Consent Form
No - There is not a plan to make this available

Clinical Study Report
No - There is not a plan to make this available

Analytic Code
No - There is not a plan to make this available

Data Dictionary
No - There is not a plan to make this available